IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
EASTERN DIVISION

Maryann Laird,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION**
	)	
Indevus Pharmaceuticals, Inc., F/K/A Interneuron Pharmaceuticals, Inc.; Wyeth, Inc., F/K/A American Home Products Corporation; Wyeth Pharmaceuticals, Inc. F/K/A Wyeth-Ayerst Pharmaceuticals, Inc., A Division of American Home Products Corporation; and Boehringer Ingelheim Pharmaceuticals, Inc.	)	**NO.** 04cv11040-GAO
	)	
Defendants.	)	

NOTICE OF REMOVAL

Defendant Wyeth, formerly known as American Home Products Corporation and including defendant Wyeth Pharmaceuticals, Inc. (formerly known as Wyeth-Ayerst Pharmaceuticals, Inc.), files this Notice of Removal removing this action from the Superior Court of the Commonwealth of Massachusetts, Middlesex County, to the United States District Court for the District of Massachusetts, Eastern Division.

Preliminary Statement

Plaintiff alleges that she was injured by the diet drugs fenfluramine (Pondimin®) and dexfenfluramine (Redux™). Wyeth sold Pondimin and Redux. Indevus Pharmaceuticals, Inc., ("Indevus")[1] was involved in the development and marketing of Redux, but not Pondimin.

[1] Indevus was known as Interneuron Pharmaceuticals, Inc., until April 2002.

Boehringer Ingelheim Pharmaceuticals, Inc ("Boehringer") was involved in the production of Redux, but not Pondimin.

All federal diet drug cases have been consolidated before the United States District Court for the Eastern District of Pennsylvania (the "MDL Court") since 1997. The MDL Court has developed substantial expertise with respect to the legal and scientific issues presented in diet drug cases. In 2000, the MDL Court approved a nation-wide class action settlement (the "National Settlement"). The settlement class includes all diet drug users except for those who opted out of the class. Plaintiff alleges that, although she is a member of the settlement class, she may sue under provisions of the National Settlement that permit class members to file lawsuits in certain circumstances.[2]

There has been an explosion of cases in the diet drug litigation in which plaintiffs attempt to evade the MDL Court by filing lawsuits in state court, fraudulently joining resident or non-diverse defendants against whom there is no reasonable possibility of recovery and no good-faith intent to pursue a claim, and misjoining in one complaint the claims of dozens or even hundreds of plaintiffs, only one, or a small number, of whom are not diverse from Wyeth. The plaintiffs' bar apparently is attempting to evade the MDL Court and remain in state courts despite the presence of diversity between the plaintiffs and Wyeth, the real defendant in these cases. The MDL Court addressed this problem in *Anderson v. American Home Products Corp.*, 220 F. Supp. 2d 414 (E.D. Pa. 2002), explaining:

[2] It is yet to be determined whether plaintiff meets the medical and other criteria for being permitted to assert such claims under the terms of the National Settlement. If she does not meet those criteria, an existing injunction entered by the MDL Court bars and enjoins plaintiff from asserting her claims. *Brown v. Am. Home Prods. Corp.*, Nos. 1203 and 99-20593, 2000 WL 1222042, at *72 (E.D. Pa. Aug. 28, 2000).

> What has been transpiring can only be characterized as a *sham*, at the unfair expense not only of AHP [now known as Wyeth] but of many individuals and small enterprises that are being unfairly dragged into court simply to prevent the adjudication of lawsuits against AHP, the real target, in a federal forum.

Id. at 425 (emphasis added). The Court cautioned that "'so long as federal diversity jurisdiction exists . . . the need for its assertion may well be greatest when plaintiff tries hardest to defeat it.'" *Id.* (quoting *Boyer v. Snap-on Tools Corp.*, 913 F.2d 108, 111 (3d Cir. 1990)).

Unfortunately, the sham that the MDL Court tried to stop in *Anderson* continues. For example, last summer, in a desperate bid to avoid the MDL Court, plaintiffs' attorneys—including several of the plaintiffs' attorneys involved in these lawsuits[3]—filed 168 cases naming more than 14,000 plaintiffs in state court in Fulton County, Georgia, even though only 5 percent of the plaintiffs were Georgia residents. The complaints each named several resident Wyeth employee defendants and one or a small number of plaintiffs non-diverse from Wyeth. The Hon. Robert L. Vining of the U.S. District Court for the Northern District of Georgia held that the resident defendants were fraudulently joined and that it was improper to join the claims of one or two plaintiffs non-diverse from Wyeth with the unrelated claims of plaintiffs from other states. Judge Vining denied plaintiffs' motions to remand, and the cases were transferred to the MDL Court for discovery. *See* Order, *In re Fen-Phen Litig.*, No. 1:03-MD-1-RLV (N.D. Ga. Oct. 14, 2003) (Exhibit 1)[4]. Judge Vining's decision followed the rationale of a decision by the MDL Court denying motions to remand in six cases involving 126 plaintiffs removed from Georgia

[3] Several of the law firms that have recently indicated that they were filing diet drug cases in Massachusetts also were involved in the plaintiffs' bar's unsuccessful efforts in Georgia to keep diet drug cases out of the MDL Court: Aylstock, Witkin & Sasser; Hackard & Holt; and Williams Bailey.

[4] Exhibits B and 1-8 to this Notice of Removal were filed in both hard copy and on CD-Rom in *Andrus et al. v. Indevus Pharmaceuticals et al.*, No. 04-CV-10911-GAO, and are incorporated here by reference.

state court. *See Weaver v. Am. Home Prods. Corp.*, No. 03-20153, Pretrial Order No. 2946 (E.D. Pa. July 30, 2003) (Exhibit 2).

With their efforts to funnel plaintiffs to Fulton County, Georgia, soundly rejected, the plaintiffs' bar is now attempting to funnel plaintiffs from around the country to Middlesex County, Massachusetts. The plaintiffs' bar has recently filed 195 cases on behalf of 2,624 plaintiffs, only 41 of whom are from Massachusetts, and has indicated its intent to file cases on behalf of a total of 4,598 plaintiffs. Most cases were filed on behalf of approximately 10-15 plaintiffs. These plaintiffs come from virtually every state in the union—from New York to California and from Florida to Maine. Plaintiffs proffer no legitimate reason for why they would bring suit in a jurisdiction as distant as 3,000 miles from their homes.

The obvious reason is to attempt to defeat federal jurisdiction. Plaintiffs name Indevus, a citizen of Massachusetts, even though plaintiffs have no reasonable basis for a claim against this defendant due to the expiration of the statute of limitations, and plaintiffs have no good faith intent to pursue a claim against Indevus, a company with limited resources that has been named in thousands of diet drug cases but has never been taken to trial or judgment. In certain cases, plaintiffs also attempt to defeat jurisdiction by naming a single plaintiff or a small number of plaintiffs who are non-diverse from Wyeth, the real defendant in this case, and then attempting to leverage that non-diversity of a single plaintiff to defeat federal jurisdiction as to all plaintiffs.

This case is part of the scheme described above. Plaintiff attempts to defeat federal jurisdiction by fraudulently joining Indevus as a defendant.

Plaintiff's ploy must fail. As demonstrated below, Indevus is fraudulently joined because plaintiff's purported claims against it are time-barred. The claims of all plaintiffs who are diverse from Wyeth belong in federal court. Wyeth anticipates that plaintiff will file a motion to

remand this case to state court. In response, Wyeth expects to file a motion to stay pending transfer to the MDL Court so that court—which is familiar with the legal and factual issues in these cases as well as the plaintiffs' bar's fraudulent joinder tactics—can decide these common issues consistently.

Pursuant to an existing MDL order, each plaintiff would be severed into a separate action. Following completion of discovery, Wyeth intends to make a motion pursuant to 28 U.S.C. § 1404 to transfer cases by those plaintiffs from jurisdictions other than Massachusetts to the federal courts in plaintiffs' jurisdictions for final disposition. This will protect Wyeth's right to be in federal court and insure that plaintiffs' claims are tried by federal courts in their own jurisdictions, where they belong.

The Complaint

1.

Wyeth is a defendant in a civil action brought against it in the Superior Court of the Commonwealth of Massachusetts, Middlesex County, entitled *Laird, et al. v. Indevus Pharmaceuticals, Inc., et al.*, bearing Civil Action No. 2004 – 01153.

2.

A copy of the Complaint and any process, pleadings and orders filed by the Parties are attached hereto as Exhibit A.

3.

The action was commenced by the filing of a Complaint on or about March 25, 2004, in the Superior Court of the Commonwealth of Massachusetts, Middlesex County.

4.

The Complaint names one plaintiff, Maryann Laird, who is a resident of Florida.

5.

The Complaint names as defendants Wyeth (formerly known as American Home Products Corporation) and Wyeth Pharmaceuticals, Inc. (formerly known as Wyeth-Ayerst Pharmaceuticals, Inc.). Another named defendant is Indevus Pharmaceuticals, Inc. (formerly known as Interneuron Pharmaceuticals, Inc.), which was involved with the development of Redux. The Complaint also names Boehringer Ingelheim Pharmaceuticals, Inc, which manufactured Redux.

6.

Wyeth is a Delaware corporation with its principal place of business in New Jersey. Wyeth Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business in Pennsylvania.

7.

Based upon the allegations of the Complaint, Indevus is a Delaware corporation with its principal place of business in Massachusetts.

8.

Based upon the allegations in the Complaint, Boehringer is a Delaware Corporation with is principal place of business in Connecticut.

Fraudulent Joinder Standard

9.

The citizenship of fraudulently joined parties is disregarded in determining the existence of diversity jurisdiction under 28 U.S.C. § 1332 and for determining whether a case may be removed under 28 U.S.C. § 1441 where there is a resident defendant. *See, e.g., Polyplastics, Inc.*

v. Transconex, Inc., 713 F.2d 876, 877 (1st Cir. 1983) ("A party fraudulently joined to defeat removal need not join in a removal petition, and is disregarded in determining diversity of citizenship."); *United Computer Sys., Inc. v. AT&T Corp.*, 298 F.3d 756 (9th Cir. 2002) (holding that removal is permissible under 28 U.S.C. § 1441 if the resident defendants are fraudulently joined).

10.

A defendant is fraudulently joined if there is no reasonable possibility of a claim against it. A "mere theoretical possibility of recovery under state law" is not enough. *Mills v. Allegiance Healthcare Corp.*, 178 F. Supp. 2d 1, 5 (D. Mass. 2001) (citing *Badon v. RJR Nabisco, Inc.*, 236 F.3d 282, 286 n.4 (5th Cir. 2000)) ("[T]here must at least be arguably a *reasonable* basis for predicting that state law would allow recovery in order to preclude a finding of fraudulent joinder."). As this Court has held, "the linchpin of the fraudulent joinder analysis is whether the joinder of the non-diverse party has a *reasonable basis in law and fact*." *Id.* at 4 (emphasis added).

11.

There is no reasonable basis for a claim against a defendant when the statute of limitations has expired. *See Ritchey v. Upjohn Drug Co.*, 139 F.3d 1313, 1320 (9th Cir. 1998) (holding that a defendant is fraudulently joined when the statute of limitations has run); *Alexander v. Wyeth*, No. 03-20206, Pretrial Order 3230, at 15 (E.D. Pa. Jan. 29, 2004) (Exhibit 3) (same); *Longden v. Philip Morris, Inc.*, 2003 WL 21975365, at *3 (D.N.H. Aug. 19, 2003) (citing *In re Diet Drugs*, 210 F. Supp. 2d 44, 422-23 (E.D. Pa. 2002)) (same).

Defendant Indevus Is Fraudulently Joined

12.

The presence of Indevus does not defeat removal because plaintiff has no reasonable basis for a claim against Indevus because any claim against Indevus is time-barred.[5] The statute of limitations on a claim seeking recovery for personal injury in Massachusetts is three years regardless of the legal theory on which the claim is brought, G.L. c. 260 § 2A, except a limitations period of four years for plaintiff's chapter 93A claims, G.L. c. 260 § 5A. The statute of limitations begins to run when plaintiff knew she was injured, or when plaintiff, with the exercise of reasonable diligence, should have known she was injured, whichever is later. "[T]he statute of limitations starts to run when an event or events have occurred that were reasonably likely to put the plaintiff on notice that someone may have caused her injury." *Bowen v. Eli Lilly & Co., Inc.*, 408 Mass. 204, 207, 577 N.E.2d 739, 741 (1990). Furthermore, if a plaintiff "invokes the discovery rule by claiming that her delay in filing suit stems from a failure to recognize the cause of her injuries, [she] bears the burden of proving both an actual lack of causal knowledge and the objective reasonableness of that lack of knowledge." *Doe v. Creighton*, 439 Mass. 281, 283, 786 N.E.2d 1211, 1213 (2003) (citing *Riley v. Presnell*, 409 Mass. 239, 243-247, 565 N.E.2d 780 (1991); *Phinney v. Morgan*, 39 Mass. App. Ct. 202, 206, 654 N.E.2d 77 (1995)).

[5] Under the Settlement Agreement, Wyeth may not plead the statute of limitations, except in certain defined circumstances. The Settlement Agreement does not limit the ability of Indevus or Boehringer (neither of which are parties to the Settlement Agreement) to plead the statute of limitations, nor the ability of Wyeth to demonstrate the fraudulent joinder of a defendant based on the expiration of the statute of limitations against that defendant. *See Amiker v. Wyeth*, No. 03-20343, Pretrial Order 3391, slip op. at 7 (E.D. Pa. April 2, 2004) (Exhibit 4).

13.

Once a plaintiff knows that she may have been harmed, she is on "inquiry notice" and has the "duty to discover from the legal, scientific, and medical communities whether the theory of causation is supportable and whether it supports a legal claim." *Bowen*, 408 Mass. at 208, 557 N.E.2d at 742 (quoting *Fidler v. Eastman Kodak Co.,* 714 F.2d 192, 199 (1st Cir. 1983)). If a plaintiff is capable of discovering a claim through "ordinary diligence," the statute of limitations begins to run at the time the duty to inquire is triggered, and not when the plaintiff actually discovers the facts necessary to support her claim against a particular defendant. *Sheila S. v. Commonwealth*, 57 Mass. App. Ct. 423, 428-29, 783 N.E.2d 868, 874 (2003) (holding that plaintiff's knowledge of government agency's involvement was sufficient, at minimum, to stimulate further inquiry into Commonwealth's potential liability, even though plaintiff did not know the facts surrounding agency's negligence).

14.

In this case, plaintiff's claims against Indevus are barred by the statute of limitations as a matter of law. The last date plaintiff could have used diet drugs was September 15, 1997, when Wyeth withdrew Pondimin and Redux from the market. Any alleged heart valve injury plaintiff suffered as a result of diet drugs occurred no later than that date because there is no evidence that heart valve damage possibly associated with diet drugs is latent, meaning that it does not develop after use of the drugs has ceased. *Brown v. Am. Home Prods. Corp.*, Nos. 1203 and 99-20593, Pretrial Order 1415, 2000 WL 1222042, at *46 (E.D. Pa. Aug. 28, 2000) (MDL Court finding "no evidence" of heart valve injuries developing later); *see also Rainey v. Wyeth*, No. 03-20128, Pretrial Order 2886, slip op. at 7 n.4 (E.D. Pa. June 12, 2003) (Exhibit 5) (MDL Court "found that there is no latency period between the time of drug use and injury"); *Alexander v. Wyeth*,

No. 03-20206, Pretrial Order 3230, slip op. at 13-14 (E.D. Pa. Jan. 29, 2004) (Exhibit 3) (citing "competent medical evidence" reviewed by Judge Bartle in concluding that diet drugs Pondimin and Redux do not create latent injuries); *French v. Wyeth*, No. 03-20353, Pretrial Order 3281, slip op. at 13 (E.D. Pa. Feb. 18, 2004) (Exhibit 6) (repeating earlier finding that valvular heart disease attributed to diet drug use is not latent). The MDL Court has held that plaintiffs are collaterally estopped from relitigating the issue of latency. *Id.* Thus, plaintiff could have discovered her injuries by September 1997 had she gone to a doctor for appropriate testing.

15.

Plaintiff was put on notice that she should obtain such testing by September 15, 1997 because of massive national and local publicity about the fact that diet drugs may cause heart valve damage. On July 8, 1997, the United States Department of Heath and Human Services issued a Health Advisory and the Mayo Clinic issued a press release concerning health risks possibly associated with the use of diet drugs. The September 15, 1997, withdrawal of the drugs from the market was accompanied by numerous press releases and advertisements. The withdrawal also was accompanied by massive publicity in the national and local media in the areas where each of the plaintiffs resides. *See* Declaration of Sharon L. Taylor (Exhibit 7).

16.

The MDL Court overseeing the diet drug litigation has held that this mass of information put plaintiffs on inquiry notice of their claims as early as September 1997. *Allen v. Wyeth*, No. 03-20310, Pretrial Order 3305, slip op. at 9 (Exhibit 8) ("[W]e find that plaintiffs can reasonably be held to have knowledge of their injuries [and] the cause of their injuries … as early as September, 1997 and at the latest by March, 2000. Thus their actions accrued and the statute of limitations began to elapse at that time.").

17.

Numerous courts have found publicity to have put plaintiffs on notice of their claims. *See United Klans of Am. v. McGovern*, 621 F.2d 152, 154-55 (5th Cir. 1980) (per curiam) (agency press conference, press release, and publication of a Senate report led to conclusion that "in the exercise of due diligence, plaintiff should have known that it had a potential claim"); *Hughes v. Vanderbilt Univ.*, 215 F.3d 543, 548-49 (6th Cir. 2000) (plaintiff should have known of potential claim where publicity was extensive); *Winters v. Diamond Shamrock Chem. Co.*, 149 F.3d 387, 403-04 (5th Cir. 1998) (as a matter of law, extensive media coverage in the mid-1980's concerning Agent Orange put plaintiff on notice at that time that she should investigate her potential claim).

18.

Plaintiff's fraudulent concealment count is no exception to the fact that plaintiff's claims against Indevus are barred by the statute of limitations. The statute of limitations will not be tolled for fraudulent concealment claims "if the plaintiff has actual knowledge of the facts giving rise to [her] cause of action" or "the means to acquire the facts on which [her] cause of action is based." *Stark v. Advanced Magnetics, Inc.*, 50 Mass. App. Ct. 226, 234, 736 N.E.2d 434, 442 (2000); *see also Burbridge v. Board of Assessors of Lexington*, 11 Mass. App. Ct. 546, 549-50, 417 N.E.2d 477, 480 (1981) (citing *Walker v. Soule*, 138 Mass. 570, 572 (1885)); *Lynch v. Signal Fin. Co.*, 367 Mass. 503, 507-08, 327 N.E.2d 732 (1975)) ("[E]stoppel provision of G.L. c. 260, s 12 is generally not available if the plaintiff is capable of discovering the facts allegedly concealed."). In this case, plaintiff not only had the means to learn of her causes of action, but is charged with knowledge of her claims as a matter of law. *See* discussion, *supra*. The fact that

thousands of plaintiffs filed personal injury claims against Indevus in 1997 and immediately thereafter shows that plaintiff had the means to discover the facts underlying her claims.

19.

Further, the supposed "concealment" alleged by plaintiff is that Indevus has denied liability in diet drug litigation. However, it is well-established that a company's mere denial of liability for a particular act does not constitute fraudulent concealment. *See Estate of Sarocco v. Gen. Elec. Co.*, 939 F. Supp. 91, 97-98 (D. Mass. 1996). "The defendants' general, repeated public denial of any link between PCB's and cancer does not constitute fraudulent concealment as a matter of law. A defendant is not obliged to acknowledge liability, or to adopt a plaintiff's theory of a case, in order to avoid a defense of this sort." *Id.* Even more specific statements concerning liability do not rise to the level of fraudulent concealment. In *Olsen v. Bell Telephone Labs, Inc.*, representatives of the defendant told the plaintiff that his condition was not permanent and that the substance at issue did not cause the plaintiff's injuries. The court refused to find that defendants' conduct rose to the level of fraudulent concealment. "Unless the defendants 'made representations they knew or should have known would induce the plaintiff to put off bringing suit and . . . the plaintiff did in fact delay in reliance on the representations,' there is no estoppel." *Olsen v. Bell Telephone Labs, Inc.*, 388 Mass. 171, 176, 445 N.E.2d 609, 612 (quoting *White v. Peabody Constr. Co.*, 386 Mass. 121, 134-35, 434 N.E.2d 1015 (Mass. 1982)).

20.

Because the statute of limitations in Massachusetts for plaintiff's claims expired years ago, plaintiff alleges that the statute of limitations was tolled during the pendency of one or more

putative class actions in which Indevus was named as a defendant. *See* Complaint ¶ 7. Plaintiff bases her allegation on a federal antitrust decision, *American Pipe & Construction Co. v. Utah*, 414 U.S. 538, 554 (1974), that has not been adopted by the Supreme Judicial Court of Massachusetts. *Massachusetts Elec. Co. v. Massachusetts Comm'n Against Discrimination*, 375 Mass. 160, 165 n.2, 375 N.E.2d 1192, 1197 n.2 (1978). Over the years, those courts that have adopted such a tolling rule have carved out numerous exceptions and limitations to the doctrine.

21.

Plaintiff has no reasonable likelihood of success on her argument that the statute of limitations was tolled because numerous independent obstacles would block any effort by plaintiff to invoke *American Pipe* tolling here.

- Neither the Supreme Judicial Court of Massachusetts nor the state legislature has adopted *American Pipe* tolling. It is highly unlikely that the Supreme Judicial Court would change the law to adopt *American Pipe* tolling in any type of case because equitable tolling is disfavored in Massachusetts. The Supreme Judicial Court has held that "[e]quitable tolling is used only sparingly, and is generally limited to specified exceptions." *Shafnacker v. Raymond James & Assocs., Inc.*, 425 Mass. 724, 728, 683 N.E.2d 662, 665 (1997) (citation omitted). *American Pipe* tolling is not one of those "specified exceptions."
- Even if Massachusetts courts might otherwise adopt *American Pipe*, it is highly unlikely that they would do so for personal injury actions. The vast majority of cases

considering the issue have rejected the application of *American Pipe* to personal injury cases.

- Even if plaintiff could persuade Massachusetts courts to adopt *American Pipe* and to do so in a personal injury case, it is overwhelming likely that the Courts would limit any tolling effect to the first class action that was filed and that plaintiff could not "stack" multiple successive class actions to toll the statute of limitations indefinitely.
- Even if plaintiff could persuade Massachusetts courts to look beyond the first filed class action, it would not help her. That is because Massachusetts courts would likely prohibit plaintiff from relying on any class action pending outside Massachusetts.
- Plaintiff could not rely on class actions of which she was not a putative class member or that did not include the claims filed in this lawsuit.
- Finally, even if plaintiff could overcome all of these and other obstacles and persuade Massachusetts courts to adopt *American Pipe* in the context of this case, it is overwhelmingly likely that the courts would adopt a rule that would require plaintiffs to refile their lawsuits within one year from the dismissal of the class action at issue.

Even if plaintiff had a reasonable chance to overcome any one of these hurdles, plaintiff's chance of overcoming each and every one of these independent hurdles is so small that the likelihood the plaintiff could persuade a court to toll the statute of limitations on her claims and to do so for the period required to make her claims timely is remote and theoretical at best. Such a remote and theoretical possibility does not constitute a reasonable basis for a claim. Accordingly, Indevus is fraudulently joined as claims against it are barred by the statute of

limitations. If the Court has any doubt that Indevus is fraudulently joined, it should permit limited discovery directed solely to the limitations issue.

This Case Satisfies The Other Requirements For Diversity Jurisdiction And Removal

22.

Based on the allegations and claims in the Complaint, the matter in controversy exceeds the sum of $75,000 exclusive of interest and costs and is a civil action brought in a state court over which the United States District Court has original jurisdiction because there is both a diversity of citizenship between the properly joined parties and the amount in controversy meets the monetary requirements under 28 U.S.C. § 1332.

23.

All properly joined and served defendants in this case consent to this Notice of Removal. *See* Exhibit B. Fraudulently joined defendants do not have to consent to the Notice of Removal. *See Polyplastics, Inc. v. Transconex, Inc.*, 713 F.2d 876 (1st Cir. 1983) ("A party fraudulently joined to defeat removal need not join in a removal petition, and is disregarded in determining diversity of citizenship.").

24.

The pending action is one that may be removed to this Court, and this Notice of Removal is filed pursuant to 28 U.S.C. § 1441 et seq.

25.

After the filing of this Notice of Removal, Petitioners will promptly give notice thereof to Plaintiff and will file a true and correct copy of this Notice of Removal with the Superior Court of the Commonwealth of Massachusetts, Middlesex County.

WHEREFORE, Petitioners pray that this Notice of Removal be filed; that said action being Civil Action No. 2004 – 01153 in the Superior Court of the Commonwealth of Massachusetts, Middlesex County, be removed to this Court; and that no further proceedings be had with respect to those claims in the Superior Court of the Commonwealth of Massachusetts, Middlesex County.

Respectfully submitted this 21st day of May 2004.

/s/ Janice W. Howe
William A. McCormack BBO #329580
Janice W. Howe BBO #242190
David Yamin BBO #562216
Bingham McCutchen LLP
150 Federal Street
Boston, MA 02110
(617) 951-8000

Counsel for Defendants Wyeth and Wyeth Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

This is to certify that I have this day served the within and foregoing NOTICE OF REMOVAL upon all parties to the above-captioned action by depositing a copy of same in the United States Mail in a properly addressed envelope with sufficient postage affixed thereto to ensure delivery to the following:

Edward J. Barshak (BBO No. 032040)
Michael S. Appel (BBO No. 543898)
Sugarman, Rogers, Barshak & Cohen, P.C.
101 Merrimac Street, 9th Floor
Boston, MA 02114

K. Stephen Jackson
Joseph L. Tucker
K. Stephen Jackson, P.C.
2229 First Avenue North
Birmingham, AL 35203

Counsel for Plaintiff

Matthew J. Matule (BBO #632075)
Skadden, Arps, Slate, Meagher & Flom LLP
One Beacon Street
Boston, Massachusetts 02108

Counsel for Defendants Indevus Pharmaceuticals, Inc. and Boehringer Ingelheim Pharmaceuticals, Inc.

This 21st day of May, 2004.

/s/ Janice W. Howe

Counsel for Defendants Wyeth and Wyeth Pharmaceuticals, Inc

EXHIBIT A

CIVIL ACTION COVER SHEET

DOCKET NO.(S) 04-1153

Trial Court of Massachusetts
Superior Court Department
County: Middlesex

PLAINTIFF(S)	DEFENDANT(S)
See List of Plaintiffs Attached	See List of Defendants Attached
ATTORNEY, FIRM NAME, ADDRESS AND TELEPHONE See List of Attorneys Attached Board of Bar Overseers number:	ATTORNEY (if known)

Origin code and track designation

Place an x in one box only:

- [X] 1. F01 Original Complaint
- [ ] 2. F02 Removal to Sup.Ct. C.231,s.104 (Before trial) (F)
- [ ] 3. F03 Retransfer to Sup.Ct. C.231,s.102C (X)
- [ ] 4. F04 District Court Appeal c.231, s. 97 &104 (After trial) (X)
- [ ] 5. F05 Reactivated after rescript; relief from judgment/Order (Mass.R.Civ.P. 60) (X)
- [ ] 6. E10 Summary Process Appeal (X)

TYPE OF ACTION AND TRACK DESIGNATION (See reverse side)

CODE NO.	TYPE OF ACTION (specify)	TRACK	IS THIS A JURY CASE?
B05	Product Liability	(A)	(X) Yes ( ) No

The following is a full, itemized and detailed statement of the facts on which plaintiff relies to determine money damages. For this form, disregard double or treble damage claims; indicate single damages only.

TORT CLAIMS

(Attach additional sheets as necessary)

A Documented medical expenses to date: **Expenses Listed are per Plaintiff**

1. Total hospital expenses not yet determined ..... $
2. Total Doctor expenses see above ..... $
3. Total chiropractic expenses ..... $
4. Total physical therapy expenses ..... $
5. Total other expenses (describe) not yet determined ..... $

Subtotal $

B. Documented lost wages and compensation to date not yet determined ..... $

C Documented property damages to date ..... $

D. Reasonably anticipated future medical and hospital expenses approximately ..... $ 575,000.00

E. Reasonably anticipated lost wages ..... $

F Other documented items of damages (describe)

$

G Brief description of plaintiff's injury, including nature and extent of injury (describe)

Each individual Plaintiff has suffered injuries & damages including, but not strictly limited to, heart-valve disease, heart-valve regurgitation, elevated pulmonary hypertension, physical pain & suffering, and mental anguish. $ 575,000.00

TOTAL $1,150,000.00 per Plaintiff

CONTRACT CLAIMS

(Attach additional sheets as necessary)

Provide a detailed description of claim(s):

FILED
IN THE OFFICE OF THE
COURTS
MAR 25 2004
CLERK

TOTAL $. .....

PLEASE IDENTIFY, BY CASE NUMBER, NAME AND COUNTY, ANY RELATED ACTION PENDING IN THE SUPERIOR COURT DEPARTMENT

"I hereby certify that I have complied with the requirements of Rule 5 of the Supreme Judicial Court Uniform Rules on Dispute Resolution (SJC Rule 1:18) requiring that I provide my clients with information about court-connected dispute resolution services and discuss with them the advantages and disadvantages of the various methods."

Signature of Attorney of Record _____ DATE: 3/22/04

AOTC-6 mic005-11/99
A.O.S.C. 1-2000

CIVIL ACTION COVER SHEET INSTRUCTIONS

SELECT CATEGORY THAT BEST DESCRIBES YOUR CASE

	CONTRACT			REAL PROPERTY			MISCELLANEOUS	
A01	Services, labor and materials	(F)	C01	Land taking (eminent domain)	(F)	E02	Appeal from administrative Agency G.L. c. 30A	(X)
A02	Goods sold and delivered	(F)	C02	Zoning Appeal, G.L. c.40A	(F)	E03	Action against Commonwealth Municipality, G.L. c.258	(A)
A03	Commercial Paper	(F)	C03	Dispute concerning title	(F)	E05	All Arbitration	(X)
A08	Sale or lease of real estate	(F)	C04	Foreclosure of mortgage	(X)	E07	c.112,s.12S (Mary Moe)	(X)
A12	Construction Dispute	(A)	C05	Condominium lien and charges	(X)	E08	Appointment of Receiver	(X)
A99	Other (Specify)	(F)	C99	Other (Specify)	(F)	E09	General contractor bond, G.L. c.149,s.29,29a	(A)
	TORT			EQUITABLE REMEDIES		E11	Workman's Compensation	(X)
B03	Motor Vehicle negligence-personal injury/property damage	(F)	D01	Specific performance of contract	(A)	E14	Chapter 123A Petition-SDP	(X)
B04	Other negligence-personal injury/property damage	(F)	D02	Reach and Apply	(F)	E15	Abuse Petition, G.L.c.209A	(X)
B05	Products Liability	(A)	D06	Contribution or Indemnification	(F)	E16	Auto Surcharge Appeal	(X)
B06	Malpractice-medical	(A)	D07	Imposition of Trust	(A)	E17	Civil Rights Act, G.L.c.12,s.11H	(A)
B07	Malpractice-other(Specify)	(A)	D08	Minority Stockholder's Suit	(A)	E18	Foreign Discovery proceeding	(X)
B08	Wrongful death,G.L.c.229,s2A	(A)	D10	Accounting	(A)	E96	Prisoner Cases	(F)
B15	Defamation (Libel-Slander)	(A)	D12	Dissolution of Partnership	(F)	E97	Prisoner Habeas Corpus	(X)
B19	Asbestos	(A)	D13	Declaratory Judgment G.L.c.231A	(A)	E99	Other (Specify)	(X)
B20	Personal Injury-Slip&Fal	(F)						
B21	Environmental	(A)						
B22	Employment Discrimination	(F)						
B99	Other (Specify)	(F)						

TRANSFER YOUR SELECTION TO THE FACE SHEET.

EXAMPLE:

CODE NO.	TYPE OF ACTION (SPECIFY)	TRACK	IS THIS A JURY CASE?
B03	Motor Vehicle Negligence-Personal Injury	(F)	☒ Yes ☐ No

SUPERIOR COURT RULE 29

DUTY OF THE PLAINTIFF. The plaintiff or his/her counsel shall set forth, on the face sheet (or attach additional sheets as necessary), a statement specifying in full and itemized detail the facts upon which the plaintiff then relies as constituting money damages. A copy of such civil action cover sheet, including the statement as to the damages, shall be served on the defendant together with the complaint. If a statement of money damages, where appropriate is not filed, the Clerk-Magistrate shall transfer the action as provided in Rule 29(5)(C).

DUTY OF THE DEFENDANT. Should the defendant believe the statement of damages filed by the plaintiff in any respect inadequate, he or his counsel may file with the answer a statement specifying in reasonable detail the potential damages which may result should the plaintiff prevail. Such statement, if any, shall be served with the answer.

A CIVIL ACTION COVER SHEET MUST BE FILED WITH EACH COMPLAINT, BUFF COLOR PAPER.

FAILURE TO COMPLETE THIS COVER SHEET THOROUGHLY AND ACCURATELY MAY RESULT IN DISMISSAL OF THIS ACTION.

ATTACHMENT TO CIVIL ACTION COVER SHEET

List of Plaintiffs:	**List of Defendants:**
Maryann Laird	Indevus Pharmaceuticals, Inc., F/K/A Interneuron Pharmaceuticals, Inc.; Wyeth, Inc., F/K/A American Home Products Corporation; Wyeth Pharmaceuticals, Inc F/K/A Wyeth-Ayerst Pharmaceuticals, Inc., A Division Of American Home Products Corporation; Boehringer Ingelheim Pharmaceuticals, Inc.,
List of Attorneys (for Plaintiffs):	
Edward J. Barshak, (BBO No. 032040) Michael S. Appel, (BBO No. 543898) Sugarman, Rogers, Barshak & Cohen, P.C. 101 Merrimac Street, 9th Floor Boston, MA 02114 (617) 227-3030 K. Stephen Jackson Joseph L. Tucker, Esquire K. Stephen Jackson, P.C. Black Diamond Building 2229 First Avenue North Birmingham, AL 35203	

COMMONWEALTH OF MASSACHUSETTS

EASTERN COUNTIES, SS. SUPERIOR COURT

MIDDLESEX, SS.

04-1153

IN RE MASSACHUSETTS STATE COURT DIET DRUG LITIGATION
Maryann Laird; Plaintiffs v. **Indevus Pharmaceuticals, Inc., F/K/A Interneuron Pharmaceuticals, Inc.; Wyeth, Inc., F/K/A American Home Products Corporation; Wyeth Pharmaceuticals, Inc F/K/A Wyeth-Ayerst Pharmaceuticals, Inc., A Division Of American Home Products Corporation; and Boehringer Ingelheim Pharmaceuticals, Inc.,** Defendants

Civil Action
No. 00-9999-G

FILED
IN THE OFFICE OF THE
CLERK OF THE COURTS
MAR 25 2004
CLERK

COMPLAINT

Plaintiff, as named herein (collectively referred to as "Plaintiffs"), by and through their undersigned counsel, sue Defendants, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc.; Wyeth, Inc. f/k/a American Home Products Corporation; Wyeth Pharmaceuticals, Inc. f/k/a Wyeth-Ayerst Phamaceuticals, Inc., a Division of American Home Products Corporation; and Boehringer Ingelheim Pharmaceuticals, Inc. and upon information and belief, allege as follows:

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SURCHARGE 15.00
SECC 20.00
041153 #
SUBTTL 275.00
TOTAL 275.00
CHECK 275.00

Plaintiff's Allegations

1. Plaintiff files this action against the named Defendants for injuries, including but not limited to valvular heart disease ("VHD"), secondary pulmonary hypertension, and other associated injuries suffered by Plaintiffs as a result of their ingestion of the defective and dangerous pharmaceutical diet drugs Redux™ and Pondimin® ("Diet Drugs") which were researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold by Defendants, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc. ("Interneuron" or "Defendant"); Wyeth, Inc. f/k/a American Home Products Corporation ("Wyeth Defendant" or "Defendant"); Wyeth Pharmaceuticals, Inc. f/k/a Wyeth-Ayerst Phamaceuticals, Inc. ("Wyeth Defendant" or "Defendant"); and Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer" or "Defendants") as more fully detailed herein below.

2. This action is brought on behalf of the following Plaintiff, **Maryann Laird**, is a citizen and resident of Pensacola, FL suffering from VHD as a result of the ingestion, consumption and use of the Diet Drugs and is at risk of developing or is already suffering from secondary pulmonary hypertension and other related conditions as a direct and proximate result of said ingestion, consumption and use.

3. The Plaintiff was prescribed and did ingest dexfenfluramine, sold under the brand name Redux™. As well, upon information and belief, some of the Plaintiffs also ingested fenfluramine, sold under both the generic name fenfluramine and the brand name Pondimin®, comprised of dexfenfluramine as its sole active ingredient.

4. Plaintiff meets all medical criteria to qualify as intermediate and/or back-end opt-outs to the National Settlement. Specifically, Plaintiff's echocardiograms, all of which were read and interpreted by board-certified cardiologists, demonstrate that they meet the definition of FDA positive heart valve regurgitation as defined by the National Settlement. Plaintiffs have properly exercised intermediate

and/or back-end opt-out rights by completing, signing and timely submitting an opt-out form to the Settlement Court, the Trustees, and/or the Claims Administrator(s) and to the Wyeth Defendants. By filing this Complaint, Plaintiffs assert only those claims and is seeking only those damages as are permitted under the National Settlement. No other language in this Complaint shall be interpreted as Plaintiffs' intent to do otherwise. All aspects of this action are consistent with Plaintiffs' rights as an intermediate and/or back-end opt-out from the National Class Action Settlement.

5. Plaintiff named herein has filed this lawsuit within any applicable statute of limitations period.

6. Plaintiff named herein acted with diligence in attempting to discover any injury caused by their ingestion of the Diet Drugs, including following the advise of their physicians, monitoring their symptoms, and following the recommendations of the American Medical Association, American College of Cardiology, American Heart Association, American Society of Echocardiography, United States Department of Health and Human Services, and the National Diet Drug Settlement. Such Plaintiffs did not and could not have discovered their injury until they had an echocardiogram demonstrating the presence of FDA positive valvular heart disease, and could not have brought a cause of action against any of the named Defendants, including Defendant Interneuron until such Plaintiffs discovered that any injury detected was a result of the action and/or omissions of the named Defendants, including Defendant Interneuron.

7. Any statute of limitations period which applies to the Plaintiff's claims against Defendant Interneuron, have been tolled under the principles of class action tolling as recognized by the Appeals Court of Massachusetts in *DiCerbo v. Commissioner Of The Department Of Employment And Training*, 54 Mass.App.Ct. 128, 763 N.E.2d 566 (Mass.App.Ct. 2003), citing *American Pipe & Constr. Co. v. Utah*, 414 U.S. 538, 554, 94 S.Ct. 756, 38 L.Ed.2d 713 (1974) and *Crown, Cork & Seal Co. v. Parker,*

462 U.S. 345, 353-354, 103 S.Ct. 2392, 76 L.Ed.2d 628 (1983), as multiple class actions against Interneuron have been filed in state and federal courts across the country, bringing claims which are substantially the same as those claims brought in this lawsuit, including the class action complaint, *Doherty et al, v. Interneuron, et al,* No. 98-0028-C, filed in Massachusetts state court in 1998 and which remained pending through the summer of 2001. Any effort by Defendant Wyeth to remove this case based on the principle of the fraudulent joinder of Defendant Interneuron is, therefore, an improvident removal, done solely to deprive Plaintiff of her right to bring her claims in the forum of her choice.

INTRODUCTION

8. The Diet Drugs which Plaintiffs were prescribed and ingested, and which caused Plaintiffs to suffer valvular heart disease and associated injuries, were defective and unreasonably dangerous in that the Diet Drugs: were not reasonably safe for their intended use as a weight loss drugs; subjected Plaintiffs to risks which exceeded the benefits of the Diet Drugs, if any; were defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect; were more dangerous than other risks associated with obesity and/or weight loss; and were otherwise defective and unreasonably dangerous as set forth herein.

9. The defective and unreasonably dangerous Diet Drugs caused Plaintiffs to suffer from valvular heart disease and resultant injuries and damages. Valvular heart disease ("VHD") is a serious and potentially fatal disease marked by the improper backward flow or "regurgitation" of blood within in the heart's chambers and blood vessels caused by the failure of the heart's valves, which separate the heart's chambers, from properly closing. When the heart's valves fail to close sufficiently, a common result of Diet Drug ingestion, this causes the regurgitation of blood back into the chamber from which it has been pumped altering the hemodynamics within the heart. Such regurgitation is a progressive condition causing the heart to work harder to supply the body with adequate blood and oxygen. As the

heart muscle is forced to over-work, physiological and morphological changes occur whereby the heart muscle becomes enlarged and distorted in shape. As a consequence, conditions and injuries suffered as a result of these and similar Diet Drug induced changes in the heart include but are not limited to: congestive heart failure, pulmonary hypertension, valve replacement surgery, and/or death.

10. Before the Plaintiffs were prescribed and ingested the Diet Drugs which caused them to suffer VHD and associated injuries, Defendants knew or should have known that the Diet Drugs had been related to and associated with these serious and life threatening side effects. The Defendants had an obligation under the law to disclose the association between their products and VHD.

11. Due to Defendants' failure to adequately warn the FDA and doctors prescribing the Diet Drugs of the known risks of VHD, Plaintiffs' physicians were unable to inform Plaintiffs of the true risks associated with the ingestion of the Diet Drugs including VHD. These side effects were known or should have been known to Defendants at the time that they marketed the drugs to the public based on, among other things, adverse event reports, clinical studies and the medical evidence of dangerous and potentially fatal side effects from the use of the drugs in Europe and elsewhere. Defendants did not, however, conduct adequate testing to establish the safety of the drugs before marketing them nor did Defendants perform adequate post-marketing surveillance and monitoring which would have otherwise prevented Plaintiffs' injuries. Rather, the Defendants through their marketing and promotional campaigns downplayed and/or obfuscated evidence of the serious and potentially fatal side effects that consumers of these drugs could face.

Defendants

12. Defendant, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc. ("Interneuron") has its principal place of business at the Ledgemont Center, 99 Hayden Avenue, Lexington, Massachusetts and is incorporated in the State of Delaware. At all times relevant hereto,

Interneuron was engaged in the business of researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling the pharmaceutical diet drug Redux. At all times relevant hereto, Interneuron researched, formulated, tested, developed, designed, licensed, assembled, compounded, marketed, promoted, distributed, detailed, and/or sold Redux through interstate commerce through the use of its employees and/or agents including Interneuron's field sales representative force or detailers who made direct contact with physicians including Plaintiffs' prescribing doctors. Beginning in or about 1989, Interneuron researched, created, formulated, tested, developed, designed, and/or licensed Redux. On or about November 19, 1992, Interneuron entered into a joint venture or partnership with American Cyanamid Company ("American Cyanamid" or "Wyeth Defendants"), a predecessor company to the Wyeth Defendants, and Les Laboratories Servier ("Servier") pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, marketing, labeling, promotion and sale of Redux. On or about November 21, 1995, Defendant, Interneuron, entered into an exclusive "Contract Manufacturing Agreement" with Defendant, Boehringer, by which Boehringer agreed to manufacture, develop, test, assemble, package, label, prepare and/or supply Redux exclusively for and/or to Defendant, Interneuron, including supplying Defendant, Interneuron, with all of its requirements of Redux for ultimate sale in the United States including the State of Massachusetts. On or about June 1, 1996, Interneuron entered into a "Co-promotion Agreement" with the Wyeth Defendants which both reaffirmed the pre-existing joint venture or partnership between Interneuron and the Wyeth Defendants and provided for Interneuron to market, promote, advertise, distribute, label, detail, supply, package and/or sell Redux in consideration for the payments from Interneuron's co-promoter, Wyeth Defendants, for percentages of profit derived from sales generated by Interneuron's sales representative sales force. At all times material hereto, Interneuron does and did business in the State of Massachusetts and researched, created, formulated,

tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

13. The Defendant, Wyeth, Inc., f/k/a American Home Products Corporation, is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey. At all times material hereto, this Defendant manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold the pharmaceuticals known as Pondimin and Redux. A.H. Robins Company, Incorporated ("A.H. Robins") was a corporation, organized and existing under the laws of the State of Delaware, which manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold Pondimin for many years between 1973 and 1990. A.H. Robins had its principal place of business in the State of Virginia until at least 1990, when it was acquired by American Home Products Corporation, now known as Wyeth, which company has assumed all responsibility for any liability of A.H. Robins arising from its manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Pondimin. On or about November 19, 1992, Wyeth, Inc., through another predecessor company, American Cyanamid, whose assets and liabilities it later acquired, entered into a joint venture or partnership with Interneuron Pharmaceuticals, Inc. and Servier pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux and at all times material was engaged in a joint venture or partnership with Interneuron Pharmaceuticals, Inc., Servier, and Boehringer Ingelheim, Inc., in the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux. On or about June 1, 1996, this Defendant entered into a "Co-promotion

Agreement" with Interneuron Pharmaceuticals, Inc. that reaffirmed the joint venture or partnership between this Defendant and Interneuron Pharmaceuticals, Inc. At all times material hereto, this Defendant does and did business in the State of Massachusetts and researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Pondimin and Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

14. The Defendant, Wyeth Pharmaceuticals, f/k/a Wyeth-Ayerst Laboratories, Inc., is a Delaware Corporation with its principal place of business at 555 Lancaster Avenue, St. Davids, Pennsylvania. At all times material hereto, this Defendant manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold the pharmaceuticals known as Pondimin and Redux. A.H. Robins was a corporation, organized and existing under the laws of the State of Delaware, which manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold Pondimin for many years between 1973 and 1990. A.H. Robins had its principal place of business in the State of Virginia until at least 1990, when it was acquired by American Home Products Corporation, now known as Wyeth, which company has assumed all responsibility for any liability of A.H. Robins arising from its manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Pondimin. On or about November 19, 1992, Wyeth, Inc., through another predecessor company, American Cyanamid, whose assets and liabilities it later acquired, entered into a joint venture or partnership with Interneuron Pharmaceuticals, Inc. and Servier pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux and at all times material was engaged in a joint venture or partnership with

Interneuron Pharmaceuticals, Inc., Servier, and Boehringer Ingelheim, Inc., in the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux. On or about June 1, 1996, this Defendant entered into a "Co-promotion Agreement" with Interneuron Pharmaceuticals, Inc. that reaffirmed the joint venture or partnership between this Defendant and Interneuron Pharmaceuticals, Inc. At all times material hereto, this Defendant does and did business in the State of Massachusetts and researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Pondimin and Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

15. The Defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), is a Delaware Corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. At all times material hereto, this Defendant was in the business of manufacturing, assembling, developing and/or supplying the pharmaceutical known as Redux. On or about November 21, 1995, Defendant, Boehringer, entered into an exclusive "Contract Manufacturing Agreement" with Defendant, Interneuron, by which Boehringer agreed to manufacture, develop, test, assemble, package, label, prepare and/or supply Redux exclusively for and/or to Defendants, Interneuron and Wyeth Defendants, including supplying Defendants Interneuron and the Wyeth Defendants, with all of its requirements of Redux for sale in the United States. At all times material hereto, Boehringer does and did business in Massachusetts and manufactured, developed, tested, assembled, packaged, labeled, prepared and/or supplied Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs. Upon information and belief, the Redux ingested by Plaintiffs was manufactured, developed, tested, assembled, packaged, labeled, prepare and/or supplied by Boehringer.

Though "Diet Drugs" as provided herein shall otherwise include both Redux and Pondimin, all allegations referencing "Diet Drugs" as set forth herein relating to Boehringer shall only relate to Redux.

Factual Background

16. Aminorex, discovered in 1960 by United States pharmaceutical company, McNeil Laboratories, was a drug from the same family of drugs as fenfluramine and dexfenfluramine. Aminorex was touted as a wonder weight loss drug which, like fenfluramine and dexfenfluramine, worked by increasing brain serotonin while inhibiting reuptake of serotonin.

17. Fenfluramine is made up of two "mirror image" halves or isomers: dexfenfluramine (right-handed isomer or d-isomer), the isomer which increases the release and prevents the reuptake of serotonin in the brain, thereby presumably reducing appetite, and levofenfluramine (left-handed isomer or l-isomer), which increases dopamine release but can cause the unwanted side-effect of drowsiness.

18. In 1963, Science Union & Co., an affiliate of Servier, entered into a licensing agreement with Wyeth Defendants' predecessor, A.H. Robins, giving it the right to market, promote, distribute, detail, sell or otherwise profit from the sale of fenfluramine in the United States.

19. In 1965, after securing authorization for the marketing of fenfluramine in Europe, Servier commenced the sale of products containing fenfluramine in Europe. This same year, Aminorex was introduced into the European market.

20. However, by 1967, evidence began to surface that the ingestion of Aminorex was associated with pulmonary hypertension. Over the next five years, Aminorex caused in Europe a ten-fold increase in pulmonary hypertension cases, permanent injury to patients who suffered significant oxygen deprivation, and numerous deaths. In light of the reports of Aminorex induced pulmonary hypertension, McNeil Laboratories prudently suspended its research and efforts to bring Aminorex to the United States market. By 1972, Aminorex was removed from the European market.

21. In or about 1970, during the European experience, Dr. Richard Wurtman, a faculty member of the Massachusetts Institute of Technology (MIT) and the founder of Interneuron secured a United States patent for use of fenfluramine as a diet drug. Like Aminorex, Fenfluramine was touted as a wonder weight loss drug designed to effect weight loss by increasing brain serotonin while inhibiting reuptake of serotonin. The patent and rights to market fenfluramine as an obesity drug were thereafter sub-licensed by Dr. Wurtman and/or MIT to Servier.

22. Despite the European experience, in June of 1973, fenfluramine was introduced into the United States market by A.H. Robins which sold fenfluramine under the brand name Pondimin. However, after introduction into the United States market, sales of fenfluramine languished both because of restrictions in prescribing under the Controlled Substance Act and because the fenfluramine isomer levofenfluramine caused users to become lethargic and tired when using Pondimin alone.

23. In 1977, Finnish researchers found a causal link between fenfluramine/ dexfenfluramine and heart valve lesions. Based on a study of weight-loss drugs including Aminorex and fenfluramine/dexfenfluramine and their effects on the release of serotonin, it was discovered that not only was the concentration of free serotonin in the blood vessels of the lungs caused by the weight-loss drug responsible for pulmonary hypertension, but also that the vessel wall-thickening mechanism which caused pulmonary hypertension was likely the identical mechanism which caused right-sided heart valve thickening and regurgitation in carcinoid patients.

24. Recognizing the problems in selling fenfluramine caused by the levofenfluramine isomer which caused users to become lethargic and tired, in or about 1980, Servier discovered a commercially feasible way to chemically isolate and separate the active ingredient in fenfluramine, being the right-sided d-isomer (dexfenfluramine) from the undesirable left-sided isomer (levofenfluramine) and commissioned and/or contracted Dr. Wurtman and/or MIT to further research, formulate, test, develop,

design, license, assemble, compound, manufacture, market, promote, advertise, distribute, label, detail, supply, package and/or sell Redux for the United States market. This same year, MIT and/or Dr. Wurtman, secured a United States patent for use of dexfenfluramine as an obesity drug and thereafter, as with fenfluramine a decade earlier, sub-licensed the patent back to Servier.

25. On October 3, 1981, Dr. J.G. Douglas published *Pulmonary Hypertension and Fenfluramine* in the British Medical Journal. On January 25, 1986 an article entitled *Irreversible Pulmonary Hypertension after Treatment with Fenfluramine*, was published in the British Medical Journal. Defendants knew, or should have known, of the British Medical Journal articles and how those articles related to fenfluramine and dexfenfluramine, and their propensity to cause valvular heart disease, and secondary pulmonary hypertension.

26. While the sales of Pondimin languished between 1973 and 1984, sales of Pondimin increased, however, after several studies or reports sponsored, subsidized, and/or supported by the Wyeth Defendants' predecessor, A.H. Robins, were published within the medical community. Specifically, in 1984, Dr. Michael Weintraub published *A Double-Blind Clinical Trial in Weight Control: Use of Fenfluramine and Phentermine Alone and in Combination* in the Archives of Internal Medicine. Dr. Weintraub's study was sponsored, subsidized, and/or supported by A.H. Robins (later acquired by the Wyeth Defendants). Despite noting some adverse effects associated with fenfluramine, Dr. Weintraub failed to examine the long-term safety of fenfluramine. Instead, the study focused on the short-term effectiveness of the drugs used individually, and in combination with phentermine.

27. In 1985, after securing authorization for the marketing of dexfenfluramine in Europe, Servier commenced the sale of products containing dexfenfluramine in Europe under the brand/trade names Adifax (in England) and Isomeride (in France).

28. In or about 1989, after MIT and Dr. Wurtman had researched, formulated, tested, developed, designed, licensed, assembled and compounded dexfenfluramine for several years in preparation for submitting dexfenfluramine for FDA approval and licensing for sale in the United States, Dr. Wurtman incorporated Defendant, Interneuron.

29. In or about 1990, Servier sub-licensed the rights to market, promote, distribute, detail, sell or otherwise profit from the sale of dexfenfluramine in the United States back to Interneuron.

30. On or about February 27, 1990, representatives from Interneuron, Wyeth Defendants and Servier convened to discuss "certain situations pertaining to Pondimin", including protocols and respective responsibilities relating to adverse event reporting and safety information, during which Servier representatives Madame Derome-Tremblay and Christine Bazantay advised the Wyeth Defendants that there was a need to update the 1972 labeling for Pondimin. However, there was no change in the labeling of Pondimin between 1990 and mid-1996.

31. In September of 1990, Servier, co-licensor of both Pondimin and Redux in coordination with Interneuron and the Wyeth Defendants, completed a study regarding the effects of fenfluramine isomers on Fisher Rats which showed significant levels of focal fibrosis in the hearts of rats treated with doses of dexfenfluramine as compared with hearts of untreated rats. Defendants knew or should have known of the Fisher Rat study and how those articles related to fenfluramine and dexfenfluramine. At the very least, Interneuron and the Wyeth Defendants knew or should have known of the results of the Fisher Rat study by March 19, 1992, the date that the study was released by Servier.

32. On March 18, 1991, Interneuron, filed a petition with the DEA requesting that fenfluramine and its isomer dexfenfluramine be removed from Schedule IV and all other controls of the Controlled Substances Act (CSA) such that, among other things, both Pondimin and Redux could be dispensed and prescribed in larger quantities and over longer incremental dosage durations. Interneuron's efforts to

gain the de-scheduling of both fenfluramine and dexfenfluramine, continued by using politicians and large anti-regulatory political action committees aimed at persuading both the DEA and FDA.

33. On or about October 25, 1991, Interneuron, through the assistance of Cato Research, Ltd. filed an Investigational New Drug Application with the FDA in furtherance of securing approval for Redux.

34. In 1992, Dr. Weintraub again published a series of articles sponsored, subsidized, and/or supported by the Wyeth Defendants in Clinical Pharmacological Therapies, in which he reported his research regarding the long term use of fenfluramine and phentermine for weight control. Dr. Weintraub's research assumed the safety of fenfluramine, and did not examine the short-term or long-term safety of the drug. The Wyeth Defendants failed to conduct or fund any studies or research regarding the long-term safety of the fenfluramine. The Wyeth Defendants, and later Interneuron, through their sales representative force, promoted Dr. Weintraub's conclusion that long term combination use of fenfluramine and phentermine was effective for the management of obesity to both physicians, and the public. As a result, sales of Pondimin began to increase dramatically.

35. On or about November 19, 1992, Interneuron entered into a joint venture or partnership with American Cyanamid, a predecessor company to the Wyeth Defendants, and Servier pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, marketing, labeling, promotion and sale of Redux.

36. On or about April 15, 1993, Interneuron and Wyeth Defendants, through their employees, agents and/or representative parties, including Dr. Bobby W. Sandage, Jr., Interneuron's Vice-President of Research and Development and employees Dukart, Hammershaimb, Gantt, Lefkowitz, Stout and Quinn of Wyeth Defendants, met with Dr. Stuart Rich, Section of Cardiology at University of Illinois at Chicago, an expert in the area of pulmonary hypertension ("PH"), to discuss the cases of PH reported

following the use of Redux and "to help put this information into perspective." Interneuron and Wyeth Defendants at this time recognized Dr. Rich as a Principal Investigator and member of the steering committee for the NIH Registry for the Characterization of PH who had reviewed approximately thirty-six (36) cases of the drug relationship between Redux and PH and further admitted that there was an association between PH and the intake of certain exogenous substances such as and including Redux. Dr. Rich advised Interneuron and Wyeth Defendants that there was an increased risk for PH which necessitated caution until more definitive information was available. This information placed or should have placed the Defendants on notice of the association between the Diet Drugs and pulmonary hypertension, and that pulmonary hypertension may be related to valvular heart disease.

37. By 1993, the Wyeth Defendants labeling for Pondimin indicated that there were only 4 reported cases of pulmonary hypertension reported in association with the drug. Yet, that same year, Dr. Francois Brenot published an article related to the association of Fenfluramine and pulmonary hypertension, in the British Heart Journal. Dr. Brenot identified 25 cases of pulmonary hypertension associated with the use of fenfluramine and/or dexfenfluramine. The Wyeth Defendants knew or should have known of the Brenot article. The Wyeth Defendants should have known by at least 1993 that Pondimin was defective and unreasonably dangerous and further that its Pondimin labeling was false.

38. On or about May 21, 1993, Interneuron filed its NDA with the FDA for the approval of Redux. In its bid for FDA's Redux approval, Interneuron and Wyeth Defendants relied upon several pivotal "studies" in its NDA, including but not limited to, the Noble Study, the Van Itallie Study, and the Index Study.

39. Interneuron and Wyeth Defendants knew at the time of submitted the NDA for Redux to the FDA that these pivotal studies where flawed, defective and substandard, thereby effecting misrepresentations to the FDA, the medical community, Plaintiffs' prescribing physicians and Plaintiffs.

In particular, Interneuron and Wyeth Defendants were on notice through advice by Interneuron's own auditor, Bruce Sturgeon (such internal audits being typically required and expected of NDA applicants), both before and during the NDA submission and subsequent supportive documentation, that:

a. the Noble Study had careless record keeping, several protocol violations, a lack of documentation for final disposition of the drug and missing progress reports to the IRB;
b. the Van Itallie Study, which Mr. Sturgeon concluded would probably not be accepted by the FDA – though Interneuron still included the same in its NDA — included a protocol change increasing the allowable weight fluctuation from 3 kilograms to 7.5 percent of body weight without notifying the IRB or FDA, thereby reflecting a gross deviation from good clinical practices; used three patients who did not meet the revised criteria for the study; and contained inaccurate drug accountability for all patients, exacerbated by the fact that the drug was a controlled substance; and
c. the Index Study was poorly monitored, lacked proper and complete documentation, contained high error incidents in key data reporting found across all sites, and suffered from poor data quality consistent among all sampled sites which could be extrapolated to all sites in the Index Study.

40. During the time Interneuron filed its NDA for Redux, Interneuron and Wyeth Defendants knew or should have known that there were serious health risks associated with Redux which were neither sufficiently nor adequately expressed in either its NDA or its 120 Day Update.

41. By 1993, nearly two decades after the 1977 Finnish study, numerous medical reports and studies had been published within mainstream medical journals and publications firmly establishing the same causal connection between high concentrations of free circulating serotonin, as caused by fenfluramine and dexfenfluramine, and heart valve lesions, including but not limited to: Ann Redfield MM, Nicholson WJ, Edwards WD, Tajik AJ. *Valve disease associated with ergot alkaloid use: echocardiographic and pathologic correlations*. Ann Intern Med 1992;117:50-52; and Pellikka PA, Tajik AJ, Khandheria BK, et al. *Carcinoid heart disease: clinical and echocardiographic spectrum in 74 patients*. Circulation 1993;87:1188-96. As reaffirmed by these medical journal publications and their long and numerous progeny spanning nearly three decades, there was an available body of scientific

knowledge identifying the pharmacologic affects of various anorexic agents, including fenfluramine and dexfenfluramine, on circulating (release, reuptake inhibition and monoamine oxidase inhibition) serotonin. Moreover, there was an available body of scientific knowledge relating elevations in serotonin as found in ergotamine toxicity and carcinoid syndrome, like fenfluramine and dexfenfluramine, to incidents of VHD. During this period of time in which Interneuron and the Wyeth Defendants were proceeding with the Redux NDA and while the Wyeth Defendants continued to sell Pondimin on the United States market, Interneuron and Wyeth Defendants knew or should have known that fenfluramine and dexfenfluramine caused an increase in circulating serotonin and that a serotonin-related mechanism was directly associated with VHD. Interneuron and Wyeth Defendants failed to disclose the connection between the Diet Drugs and VHD and/or failed to perform pre-marketing studies and post-marketing surveillance which would have detected this fact.

42. In or about 1994, cases of heart valve damage from the use of the Diet Drugs began to appear throughout the Country including sonographer, Pamela Ruff's discovery in Fargo, North Dakota of VHD in patients who had ingested Pondimin. Numerous cases of Diet Drug induced VHD prompted physicians at the Mayo Clinic to undertake a case review which ultimately resulted in the untimely forced withdrawal of the Diet Drugs from the market.

43. In February 1994, the preliminary results of the International Primary Pulmonary Hypertension study ("IPPH Study") entitled "Appetite Suppressants and the Risk of Primary Pulmonary Hypertension" was released and available to the Defendants. The preliminary results of the IPPH Study confirmed the association between fenfluramine and dexfenfluramine and pulmonary hypertension. The Defendants failed to reveal the number of cases of pulmonary hypertension associated with the Diet Drugs to the public, Plaintiffs, or Plaintiffs' prescribing physicians.